

Applicants: Robert H. DeBellis et al.  
Serial No.: 09/828,413  
Filed: April 6, 2001  
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#### REMARKS

Claims 1-19 are pending in the subject application. Applicants have hereinabove cancelled claims 2-9 and 11-13 without prejudice or disclaimer to their right to pursue the subject matter of these claims in a later filed application. Applicants have hereinabove amended claims 1 and 14. Support for the amendments to claim 1 may be found inter alia in the specification at page 7, line 31 - page 8, line 8; and page 11, lines 13-14. The remaining changes to the claims merely introduce minor grammatical and format changes. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 1, 10 and 14-19 will be pending.

#### Formalities

The Examiner stated that this application contains claims drawn to an invention nonelected with traverse. The Examiner stated that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action.

In response, applicants point out that withdrawn claims 2-9 and 11-12 have been cancelled.

#### Claim 16

Applicants acknowledge the Examiner's statement that claim 16 is directed to allowable subject matter.

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Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1, 10, and 13-19 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner stated that insertion of the negative limitation "other than hydroxyurea" has no support in the as-filed specification.

In response, applicants respectfully traverse. Specifically, applicants note that amended claim 1 does not recite "other than hydroxyurea." In light of the above remarks, applicants maintain that claim 1, and claims 10, 14-19 which depend therefrom, satisfy the requirements of 35 U.S.C. §112, first paragraph.

Applicants note that claim 13 has been cancelled. Therefore, the rejection thereof is now moot.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections Under 35 U.S.C. §102

The Examiner stated that claims 1, 10, 17-19 are no longer

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rejected under 35 U.S.C. §102 as anticipated by Rodgers et al. or Ballas et al. in light of Lorie et al. because of the inclusion of new matter.

The Examiner stated that applicants are hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection over claims above. However, the Examiner stated that removal of the new matter will result in the reinstatement of the art rejection.

In response, applicants point out that the method of amended claim 1 does not encompass the use of hydroxyurea. Therefore, applicants maintain that claims 1, 10 and 17-19 satisfy the requirements of 35 U.S.C. §102(a) and are not anticipated by Rodgers et al. or Ballas et al. in light of Lorie et al.

The Examiner maintained the rejection of claims 1, 10, 13-15 and 17-19 under 35 U.S.C. §102(b) as allegedly anticipated by Lawson et al. The Examiner stated that the claims are directed to a one step method of treatment of a subject with sickle cell disease comprising administering an amount of an antiviral agent such as acyclovir effective to prevent sickling to treat the sickle cell disease.

The Examiner stated that Lawson et al. disclose administering acyclovir to a man with sickle cell trait. The Examiner also stated that the oral dosage is 800 mg x5. The Examiner further stated that if the person weighed about 100kg, this would be a dosage of about 400 mg/kg/day.

The Examiner alleges that because the patient is "the same",

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namely a person afflicted with sickle cell "disease"; the compound administered is the same, acyclovir, and the amount administered falls within the ranges given in the specification on page 7 for an oral dosage as being an effective dose, the result of the "treatment" must necessarily, inherently be the same. The Examiner asserts that this is an argument of inherency which applicants have not persuasively rebutted.

In response, applicants respectfully traverse. Briefly, claim 1 provides a method of treating a subject afflicted with sickle cell disease comprising administering to the subject an effective amount of an antiviral agent.

However, Lawson et al. describe the administration of acyclovir to a patient who only has sickle cell trait.

Applicants note that sickle cell disease is not equivalent to sickle cell trait. In support of their position, applicants attach hereto as Exhibit 1 a copy of a document entitled "Sickle Cell Anemia" from The Sickle Cell Information Center website sponsored by The Georgia Comprehensive Sickle Cell Center at Grady Health System, The Sickle Cell Foundation of Georgia, Inc., Emory University School of Medicine Department of Pediatrics and Morehouse School of Medicine (see <http://www.emory.edu/PEDS/SICKLE/sicklept.htm>). This document states that "if you inherit one sickle cell gene, you have sickle cell trait. If you inherit two sickle cell genes you have sickle cell disease." Furthermore, the document expressly states that sickle cell trait "will NOT cause sickle cell disease."

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Therefore, the subject described in Lawson et al. has sickle cell trait, and not sickle cell disease. Thus, the subject of Lawson et al. is not the same subject treated by the claimed method.

Lawson et al. therefore do not teach the administration of acyclovir to treat a subject afflicted with sickle cell disease, and thus fail to teach each and every element of the rejected claims.

Finally, applicants note an inadvertent misstatement in their November 17, 2003 Amendment. Specifically, on page 6 of that Amendment, applicants stated that "[t]he fact that the patient was afflicted with sickle cell disease did not prompt the doctors to administer the acyclovir." Applicants note here that that statement is incorrect because, as explained above, sickle cell trait and sickle cell disease are not equivalent. Thus, applicants' reference in the November 17, 2003 Amendment to the subject of Lawson et al. as having sickle cell disease is an inadvertent factual misstatement.

Applicants note that claim 13 has been cancelled. Therefore, the rejection thereof is now moot.

In view of the above remarks, applicants maintain that claims 1, 10, 14-15 and 17-19 satisfy the requirements of 35 U.S.C. §102(b) and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

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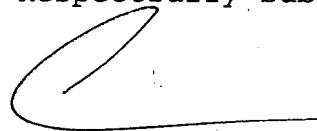
Summary

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of rejection and earnestly solicit allowance of pending claims 1, 10 and 14-19.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed \$210.00 fee for a two-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Alan J. Morrison  
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Date

7/12/07

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# The Sickle Cell Information Center

The Georgia Comprehensive Sickle Cell Center at Grady Health System

The Sickle Cell Foundation of Georgia, Inc.

University of Medicine and Dentistry of Georgia

Atlanta, Georgia

School of Medicine

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### What is Sickle Cell Anemia

## Sickle Cell Anemia

Sickle Cell anemia is a group of inherited red blood cell disorders. Normal red blood cells are round like doughnuts, and they move through small blood tubes in the body to deliver oxygen.

Sickle red blood cells become hard, sticky and shaped like sickles used to cut wheat. When these hard and pointed red cells go through the small blood tube, they clog the flow and break apart. This can cause pain, damage and a low blood count, or anemia.

### What makes the red cell sickle?

There is a substance in the red cell called hemoglobin that carries oxygen inside the cell. One little change in this substance causes the hemoglobin to form long rods in the red cell when it gives away

oxygen. These rigid rods change the red cell into a sickle shape instead of the round shape.

### How do you get sickle cell anemia or trait?

You inherit the abnormal hemoglobin from your parents, who may be carriers with sickle cell trait or

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parents with sickle cell disease. You can not catch it. You are born with the sickle cell hemoglobin and it is present for life. If you inherit only one sickle gene, you have sickle cell trait. If you inherit two sickle cell genes you have sickle cell disease.

### **Is Sickle Cell only in African Americans?**

Sickle cell is in many nationalities including African Americans, Arabs, Greeks, Italians, Latin Americans, and those from India. You can be Caucasian and have sickle cell disease or trait. All races should be screened for this hemoglobin at birth.

### **How can I be Tested?**

A simple blood test called the hemoglobin electrophoresis can be done by your doctor or local sickle cell foundation. This test will tell if you are a carrier of the sickle cell trait or if you have the disease.

### **Newborn Screening**

Most States now perform the sickle cell test babies are born. The simple blood test will detect sickle cell disease or sickle cell trait. Other types of traits that may be discovered include:

Hemoglobin C trait

Hemoglobin E trait

Hemoglobin Barts - which indicates an alpha thalassemia trait

Beta thalassemia trait

### **What is sickle cell trait?**

Sickle cell trait is a person who carries one sickle hemoglobin producing gene inherited from their parents and one normal hemoglobin gene. Normal hemoglobin is called type A. Sickle hemoglobin called S. Sickle cell trait is the presence of hemoglobin AS on the hemoglobin electrophoresis. This will NOT cause sickle cell disease. Other hemoglobin traits common in the United States are AC and AE traits.

### **Are there different types of sickle cell disease?**

There are three common types of sickle cell disease in the United States.

1. Hemoglobin SS or sickle cell anemia
2. Hemoglobin SC disease
3. Hemoglobin sickle beta-thalassemia

Each of these can cause sickle pain episodes and complications, but some are more common than others. All of these may also have an increase in fetal hemoglobin which can protect the red cell from sickling and help prevent complications. The medication hydroxyurea also increases fetal hemoglobin.



## What are the Complications? **BEST AVAILABLE COPY**

Complications from the sickle cells blocking blood flow and early breaking apart include:

1. pain episodes
2. strokes
3. increased infections
4. leg ulcers
5. bone damage
6. yellow eyes or jaundice
7. early gallstones
8. lung blockage
9. kidney damage and loss of body water in urine
10. painful erections in men (priapism)
11. blood blockage in the spleen or liver (sequestration)
12. eye damage
13. low red blood cell counts (anemia)
14. delayed growth

## What can be done to help prevent these complications?

Sickle cell patient should be under the care of a medical team that understands sickle cell disease. All newborn babies detected with sickle cell disease should be placed on daily penicillin to prevent serious infections. All of the childhood immunizations should be given plus the pneumococcal vaccine. Parents should know how to check for a fever because this signals the need for a quick medical checkup for serious infection. The following are general guidelines to keep the sickle cell patient healthy:

1. Taking the vitamin folic acid (folate) daily to help make new red cells
2. Daily penicillin until age six to prevent serious infection
3. Drinking plenty of water daily (8-10 glasses for adults)
4. Avoiding too hot or too cold temperatures
5. Avoiding over exertion and stress
6. Getting plenty of rest
7. Getting regular check-ups from knowledgeable health care providers

Patients and families should watch for the following conditions that need an urgent medical evaluation:

1. Fever
2. Chest pain
3. Shortness of Breath
4. Increasing tiredness
5. Abdominal swelling
6. Unusual headache
7. Any sudden weakness or loss of feeling
8. Pain that will not go away with home treatment
9. Priapism (painful erection that will not go down)
10. Sudden vision change

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